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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY, DOCKET NO.	CONFIRMATION NO.
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09/612,925

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Carlos Antonio Durate Cano

P-13 Div II

9520

7590

10/23/2003

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 10/23/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/612,925

Applicant(s)

DURATE CANO ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09/29/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 is/~~are~~ pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 is/~~are~~ rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 09/29/03 (paper no. 21) in response to the non-final Office Action mailed 03/26/03 (paper no. 18).

Status of Claims

- 2) Claim 11 has been amended via the amendment filed 09/29/03.
Claim 11 is pending and is under examination.

Substitute Sequence Listing

- 3) Acknowledgment is made of Applicants' substitute Sequence Listing filed 09/29/03 (paper no. 22), which has been entered (paper no. 23).

Prior Citation of Title 35 Sections

- 4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

- 6) The objection to the abstract made in paragraph 6 of the Office Action mailed 03/26/03 (paper no. 18) is withdrawn in light of Applicants' amendments to the abstract.
- 7) The objection to the specification made in paragraphs 7(a)-7(h) of the Office Action mailed 03/26/03 (paper no. 18) is withdrawn in light of Applicants' amendments to the specification.

Objection(s) Maintained

- 8) The objection to the specification made in paragraph 7(i) of the Office Action mailed 03/26/03 (paper no. 18) is maintained for reasons set forth therein. The instant specification continues to have amino acid sequence(s) that are longer than four amino acid residues in length, yet fails to fully comply with the Sequence Rules. For example, see first paragraph under Example 1.

Specification (Amended)

- 9) The amendment to the specification filed 09/29/03 is objected to under 35 U.S.C. § 132,

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because it introduces new matter into the disclosure. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows. In the first paragraph under Example 1 and second paragraph under Example 2, the limitation 'SEQ ID NO: 1' has been added. Applicants provide no explanation and reasoning as to this addition, nor do they point to support in the specification as originally filed. Applicants are required to cancel the new matter in the response to this Office Action.

Rejection(s) Withdrawn

10) The rejection of claim 11 made in paragraph 8 of the Office Action mailed 03/26/03 (paper no. 18) under 35 U.S.C. § 101 as being directed to a non-statutory subject matter, is withdrawn in light of Applicants' amendment to the claim.

11) The rejection of claim 11 made in paragraphs 10(a)-10(c) of the Office Action mailed 03/26/03 (paper no. 18) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claim.

12) The rejection of claim 11 made in paragraph 12 of the Office Action mailed 03/26/03 (paper no. 18) under 35 U.S.C. § 102(b) as being anticipated by Nazabal *et al.* (*In: Neisseria 94. Proceedings of the Ninth International Pathogenic Neisseria Conference.* (Ed) Evans *et al.* 26-30 September, Winchester, England, pages 98-99, 1994), is withdrawn in light of Applicants' amendments to the claim.

13) The rejection of claim 11 made in paragraph 14 of the Office Action mailed 03/26/03 (paper no. 18) under 35 U.S.C. § 103(a) as being unpatentable over Rodriguez *et al.* (EP 0,474,313 A2) or Niebla *et al.* (*In: Neisseria 94, Proceedings of the Ninth International Pathogenic Neisseria Conference*, (ed) Evans *et al.*, Winchester, England, 26-30 September 1994, pages 85-86), is withdrawn in light of Applicants' amendments to the claim.

Rejection(s) Maintained

14) The rejection of claim 11 made in paragraph 9 of the Office Action mailed 03/26/03 (paper no. 18) under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description with regard to the deposit issue, is maintained for part of the reason set forth therein. The amendment made to the specification provides the deposit number and the address of the

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depository, but fails to provide the date on which the hybridoma was deposited.

15) The rejection of claim 11 made in paragraph 10(d) of the Office Action mailed 03/26/03 (paper no. 18) under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein and herebelow.

The recitation in claim 11 as amended: 'the stabilizer peptide produced from the first 47 amino acids of the N-terminal end of the P64K antigen of *Neisseria meningitidis*' is still vague and indefinite because it is not clear whether the stabilizer peptide produced is a peptide of any size lesser than the first 47 amino acids, for example the first 6 amino acids, or whether the stabilizer peptide is the first 47 amino acids from the N-terminal end of the P64K antigen.

Remarks

16) Claim 11 stands rejected. It is noted that the name of the bacterium in line 6 of claim 11 is misspelled.

17) Applicants' amendment necessitated the new ground(s) of objection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

18) Papers related to this application may be submitted to Group 1600, AU 1641 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1 (CM1). The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242 which receives papers 24 hours a day, 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

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19) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

October, 2003


S. DEVI, PH.D.
PRIMARY EXAMINER